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TITLE: Treatment of Social Competence in Military Veterans, Service Members, and Civilians with Traumatic Brain Injury

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14. ABSTRACT
Impairments in social competence are among the most prevalent sequelae after traumatic brain injury (TBI). Without successful social skills a person is often isolated, in conflict with others, and denied access to social and vocational opportunities. The aim of this study is to determine the effectiveness of a manualized group treatment program to improve and maintain social competence for individuals with TBI with identified social skill deficits. The Group Interactive Structured Treatment (GIST) - Social Competence program is a holistic, dual-disciplinary intervention targeting the pervasive interpersonal and communication problems that often interfere with participation at work, home, school and in the community after TBI. During the second year of this project, all sites completed the Pilot portion of this study. The Pilot study enabled us to accomplish the following: 1) train clinicians involved on this project and give them experience and feedback implementing the GIST treatment; 2) refine the alternative intervention at Craig Hospital; 3) gain experience with the assessment tools for this project; and 4) modify the protocol for the RCT based on the experience during the Pilot. All modifications to the protocol for the RCT have been made and approved by all local IRB's and by the HRPO. Five of the six site began actively recruiting for the RCT during this second year; two sites have begun the first wave of the RCT intervention..

15. SUBJECT TERMS
Traumatic brain injury, social competence, social skills, intervention

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INTRODUCTION

Background: Impairments in social competence are among the most prevalent sequelae after traumatic brain injury (TBI). Without successful social skills a person is often isolated, in conflict with others, and denied access to social and vocational opportunities. The aim of this study is to determine the effectiveness of a manualized group treatment program to improve and maintain social competence for individuals with TBI with identified social skill deficits. The Group Interactive Structured Treatment (GIST) - Social Competence program is a holistic, dual-disciplinary intervention targeting the pervasive interpersonal and communication problems that often interfere with participation at work, home, school and in the community after TBI.

Aims and Hypotheses: Aim 1: Measure the effectiveness of the GIST intervention with multisite implementation. Hypothesis 1a: Those receiving the GIST will demonstrate significant improvement in social competence, compared to those receiving the alternative treatment, as measured by the Profile of Pragmatic Impairment in Communication (PPIC). Hypothesis 1b: Compared to the alternative intervention, those receiving the GIST will maintain improvement in social competence at 3 months post-intervention, as measured by the PPIC. Hypothesis 1c: Compared to the alternative intervention, those receiving the GIST will demonstrate improvement in additional aspects related to social competence at 3 months post-intervention, as measured by two subscales of the Behaviorally Referenced Rating System of Intermediate Social Skills-Revised, the LaTrobe Communication Questionnaire, the Goal Attainment Scale, the Brief Symptom Inventory-18, and the Post Traumatic Stress Disorder Check List – Civilian version. Hypothesis 1d: Compared to the alternative intervention, those receiving the GIST will demonstrate improvement at 3 months post intervention in quality of life, as measured by the Satisfaction with Life Scale. Aim 2: Identify the potent ingredients associated with the GIST. Hypothesis 2a: Compared to the alternative intervention, those receiving the GIST will demonstrate stronger social self efficacy associated with improved social competence, as measured by the Scale of Perceived Self Efficacy. Hypothesis 2b: For participants in the GIST intervention, higher group cohesion measured by the TFI: Cohesiveness Scale will be associated with improved social competence.

Study Design: This study uses a two-arm, multi-centered randomized controlled clinical trial design to compare the GIST treatment to an alternative treatment, in which participants are presented information from the GIST treatment program without the group process. A total of 192 military, veteran and civilian participants with mild to moderate TBI will be enrolled by six centers. Measures will be collected at baseline, post-treatment, and 3 months post-treatment. Videotapes of participants will be evaluated for social competence by blinded independent raters, and progress on individualized social skills goals will be assessed. Replicable training of group leaders will include a 2 ½ day in-person workshop followed by feedback during a pilot of the intervention and alternative intervention. The fidelity of the intervention will be assessed by independent raters using a standardized instrument to ensure that the intervention is implemented consistently. Results of this study will be disseminated to relevant stakeholders via presentations and publications. By the end of this study, the field will have definitive evidence about the effectiveness of a group social competence intervention for people with TBI.

Military Benefit: The proposed study has a high degree of relevance for returning OIF/OEF soldiers and veterans post-TBI due to the prevalence of social reintegration difficulties in this population. The GIST intervention has the potential to assist our soldiers and veterans in returning to full participation in their families, communities and productive activity.

BODY

Objective 1: Establish infrastructure for successful collaboration:

T1: Conduct Steering Committee teleconferences & local Project Site Team meetings:

ONGOING. Monthly teleconferences with all sites; bi-monthly meetings locally all documented by meeting minutes.

T2: Schedule & conduct Steering Committee via web conference:

WEB CONFERENCE not needed at this point as all coordination is occurring via monthly teleconferences.

T3: Schedule study training in Colorado:

COMPLETE.

T4: Monitor budget and study progress monthly:

ONGOING. Due to delays in startup of the RCT, due to slower than expected IRB approvals, need for additional training, and RCT recruitment, the lead site and sub-awardees carried over funds from Year 2 to Year 3, carry overs will also occur from Year 3 into Year 4 as well.

Objective II: Finalize study design, project materials, & obtain IRB approval

T1: Finalize study design, measures & interventions:

COMPLETE

T2: Submit IRB/regulatory applications per site:

COMPLETE

T3: Prepare data dictionary/syllabus & project protocols:

COMPLETE

T4: Finalize training agenda and materials:

COMPLETE

T5: Obtain IRB/regulatory approvals at each site:

COMPLETE

Objective III: Design, Test, and Implement Data Management System

T1: Design Data Management System:

COMPLETE

T2: Program data dictionary & data entry for all study measures & tracking:

COMPLETE

T3: Test/revise data management system:

COMPLETE

T4: Program data management reports:

COMPLETE. Data management reports are run internally at NDSC and each center is given instructions on data fixes.

OBJECTIVE IV: Train collaborating researchers & group therapists

T1: Train study researchers & therapists

COMPLETE. Initial training for all sites was completed in June of 2012. An additional therapist training was completed with five sites in March 2013, and with the 6th site in June 2013.

T2: Evaluate Training

COMPLETE. An additional training session for therapists after the pilot was completed was added, and ongoing treatment fidelity monitoring was increased.

T3: Training as needed for dropout of group therapists; evaluate training

ONGOING: Two sites have required training of a new therapist. One training took place on January 24, 2014 at Craig Hospital. The second new therapist training was conducted remotely and was completed in August 2014..

OBJECTIVE V: Complete pilot of study interventions & assessments

T1: Recruit/consent 8 participants per site – 16 at Craig - total of 56 for 6 sites

COMPLETE. A total of 52 participants were recruited and consented for the Pilot study as follows:

Craig Hospital – 15
Rehab Hospital of Indiana – 7
Hunter Holmes McGuire VA – 8
Palo Alto Health Care System – 7
Rehab Institute of Michigan – 7
University of Washington – 8

T2: Complete baseline testing of pilot participants

COMPLETE. Baseline testing was completed on a total of 52 participants for the Pilot study as follows:

Craig Hospital – 15
Rehab Hospital of Indiana – 7
Hunter Holmes McGuire VA – 8
Palo Alto Health Care System –7
Rehab Institute of Michigan –7
University of Washington – 8

T3: Conduct pilot interventions

COMPLETE.

T4: Complete fidelity checklist, & provide group therapists feedback at weekly calls

COMPLETE

T5: Complete post-treatment testing of pilot participants

COMPLETE Due to participant drop-out, post treatment testing was completed on a total of 33 out of 52 participants for the Pilot study as follows:

Craig Hospital – 10
Rehab Hospital of Indiana – 5
Hunter Holmes McGuire VA – 3
Palo Alto Health Care System –5
Rehab Institute of Michigan –3
University of Washington – 7

T6: Solicit/integrate feedback from participants, therapists, researchers

COMPLETE. Based on our experience during the Pilot study and on feedback and discussions with the other centers, a number of revisions were made to the original protocol to make the Randomized Controlled Trial a stronger project. All of these changes were submitted to local IRB's and HRPO for approval prior to implementation. These changes included:

1) Added an additional therapist training.

2) Dropped data collection from Significant Others (too difficult to collect, only about 25% of cases in the Pilot study).

3) Added questions about military experience to the demographics form, and added a formal measure for assessing history of TBI.

4) Replaced the Group Cohesion Scale-Revised with a simpler cohesion measure called the TFI: Cohesiveness Scale.

5) Decided not to administer the cohesion scale to the Alternative treatment group because the questions are not appropriate for this intervention which is not group oriented. (This resulted in changing hypothesis 2b which addresses the concept of group cohesion.)

6) Modified and finalized the format for the Alternative treatment.

7) Adjusted the reimbursement/compensation for participation so that individuals get some reimbursement for each session to help offset transportation costs.

T7: Update IRB approvals as needed

COMPLETE. All six sites have local IRB and HRPO approval for the RCT portion of the study.

OBJECTIVE VI: Enroll & randomize participants in study

T1: Identify, recruit & screen potential study participants

ONGOING. One site is still actively recruiting.

T2: Consent 16 eligible study participants at each of 6 sites for first wave

COMPLETE. A total of 90 participants have been consented at six sites for Wave 1 as follows:

Craig Hospital – 15
University of Washington – 16
Rehab Hospital of Indiana – 16
Hunter Holmes McGuire VA – 13
Palo Alto Health Care System – 16
Rehab Institute of Michigan – 14

T3: Randomize participants into treatment & alternative treatment

COMPLETE. A total of 90 participants have been randomized at six sites for Wave 1 as follows:

Craig Hospital – 15
University of Washington – 16
Rehab Hospital of Indiana – 16
Hunter Holmes McGuire VA – 13
Palo Alto Health Care System – 16
Rehab Institute of Michigan - 14

T4: Consent 16 eligible study participants at each of 6 sites for 2nd Wave

ONGOING. A total of 72 participants have been consented for Wave 2 at fivesites as follows:

Craig Hospital – 16
University of Washington – 16
Rehab Hospital of Indiana – 12
Hunter Holmes McGuire VA - 14
Palo Alto Health Care System – 14

T5: Randomize Wave 2 participants into treatment & alternative treatment

ONGOING. A total of 72 participants have been randomized for Wave 2 atfive sites as follows:

Craig Hospital – 16
University of Washington – 16
Rehab Hospital of Indiana – 12
Hunter Holmes McGuire VA - 14
Palo Alto Health Care System - 14

OBJECTIVE VII: Collect baseline data

T1: Administer initial baseline assessments to study participants

ONGOING. A total of 162 participants (Waves 1& 2) have completed baseline assessments as follows:

Craig Hospital – 31
University of Washington – 32
Rehab Hospital of Indiana –28
Hunter Holmes McGuire VA – 27
Palo Alto Health Care System – 30
Rehab Institute of Michigan - 14

T2: Enter baseline data into database

ONGOING: A total of 134 cases of baseline data have been entered into the database as follows:

Craig Hospital – 31
University of Washington – 32
Rehab Hospital of Indiana – 28
Hunter Holmes McGuire VA – 13
Palo Alto Health Care System – 30

OBJECTIVE VIII: Implement study intervention

T1: Complete 2 waves of treatment group intervention at each site

ONGOING. Wave 1 of treatment has been completed at five sites, and is is in progress at one site. Wave 2 of treatment has been completed at two sites and is in progress at three sites. Because Rehab Institute of Michigan has had difficulty recruiting participants for this study, they will only run one wave of the intervention. University of Washington is recruiting for a third wave of intervention to replace Michigan's second wave.

T2: Complete 2 waves of alternative intervention at each site

ONGOING. Wave 1 of alternative treatment has been completed at five sites and is in progress at one site. Wave 2 of alternative treatment has been completed at two sites and is in progress atthree sites.

OBJECTIVE IX: Implement intervention fidelity assessments

T1: Complete fidelity ratings for all GIST treatment sessions where fidelity was not met during the Pilot study and provide feedback.

ONGOING. For Wave 1 of GIST treatment, for sessions where fidelity was not met during the Pilot, 24/29 (83%) of sessions rated met fidelity. Additionally, during Wave 1, there were 5 sessions rated for fidelity because the site had a new therapist – of these 2/5 (40%) met fidelity. For Wave 2 of GIST treatment, for sessions where fidelity was not met during Wave 1, 5/5 (100%) of session rated met fidelity. For the one site

that has just begun Wave 1, there are 8 more sessions of Wave 1 to be rated for fidelity that was not met in the Pilot.

T2: Complete fidelity ratings on 4 random GIST treatment sessions

ONGOING. For Wave 1 of GIST treatment, for randomly rated sessions, 17/17 (100%) of sessions rated randomly met fidelity. For Wave 2 of GIST treatment, for randomly rated sessions, 8/9 (89%) of sessions met fidelity. There are 2 more random sessions in Wave 1 to be rated for fidelity. There are 14 more random sessions in Wave 2 to be rated for fidelity.

T3: Complete fidelity ratings on all alternative treatment sessions for Wave 1 and provide feedback.

ONGOING. For Wave 1, 45/48 (94%) of alternative treatment sessions rated met fidelity. There are 10 more alternative treatment sessions in Wave 1 to be rated for fidelity. We have continued to randomly rate fidelity for Wave 2 of the alternative treatment. For Wave 2 of the alternative treatment, 8/8 (100%) of sessions rated randomly met fidelity.

T4: Enter fidelity data into database

ONGOING

OBJECTIVE X: Collect follow-up study assessments

T1: Administer immediate post-intervention assessments to participants

ONGOING. A total of 79 post-intervention assessments have been completed as follows:

Craig Hospital – 26
University of Washington – 23
Rehab Hospital of Indiana – 11
Hunter Holmes McGuire VA – 9
Palo Alto Health Care System - 10

T2: Administer 3-month post-intervention follow-up assessments to participants

ONGOING. A total of 39 3-month post-intervention assessments have been completed as follows:

Craig Hospital – 11
University of Washington – 11
Rehab Hospital of Indiana – 9
Hunter Holmes McGuire VA - 8

T3: Enter follow-up data into database

ONGOING. A total of 79 cases of post-intervention data have been entered into the database as follows:

Craig Hospital – 26
University of Washington – 23
Rehab Hospital of Indiana – 11
Hunter Holmes McGuire VA – 9
Palo Alto Health Care System - 10

A total of 39 cases of 3-month post-intervention data have been entered into the database as follows:

Craig Hospital – 11
University of Washington – 11
Rehab Hospital of Indiana – 9
Hunter Holmes McGuire VA - 8

OBJECTIVE XI: Implement PPIC/BRISS rating system (*Note that as indicated in the Quarterly report in January 2014, the BRISS rating system, a secondary outcome measure, has been removed from the study protocol. The study investigators determined this tool did not provide any new information that was not already being captured by the PPIC, and that the BRISS rating system was too broad and abstract to train raters to be reliable in using it.)

T1: Train independent PPIC raters & establish reliability

MODIFIED/DELAYED. Training of raters will begin September2014 to coincide with completion of allvideo data collection for Wave 1 at 5 sites, and completion of all video data collection for Wave 2 at University of Washington.,

T2: Collate/randomize video tapes from each completed wave of participants

DELAYED. The first batch of video files will be randomized in September 2014 when 5 sites have completed all video data collection for Wave 1, and when University of Washington has completed all video data collection for Wave 2. The second batch of video files will be randomized when the Rehab Institute of Michigan completes all video data collection for Wave 1, University of Washington completes all video data collection for Wave 3, and all other sites complete all video data collection for Wave 2.

T3: Complete PPIC ratings on all video tapes and enter into database

DELAYED. Video ratings on the first batch of randomized video files will begin in October 2014.

OBJECTIVE XII: Analyze & interpret data

T1: Analyze & interpret baseline data

DELAYED, anticipated to begin by September, 2014.

T2: Analyze & interpret RCT data

DELAYED, anticipated to begin after March, 2015

T3: Analyze & interpret training data

NOT YET SCHEDULED TO START, and will be delayed to begin by January, 2015.

OBJECTIVE XIII Transition plan for continuity of development

T1: Give 1 or 2 presentations at national professional meetings

NOT YET SCHEDULED TO START

T2: Submit 2 articles for publication

NOT YET SCHEDULED TO START

T3: Update workbook and training program on current GIST website

NOT YET SCHEDULED TO START

T4: Conduct training workshop at a DoD Scientific meeting

NOT YET SCHEDULED TO START

T5: Collaborate with NIDRR-MSKT to produce consumer brochure on evidence base for social competence intervention

NOT YET SCHEDULED TO START

T6: Post study results and brochure for consumers on lead center website

NOT YET SCHEDULED TO START

KEY RESEARCH ACCOMPLISHMENTS

Enrollment Table

As of August 2014

SITE	Principal Investigator	HRPO Log Number (Pilot)	# Enrolled (Pilot)	HRPO Log Number (RCT)	# Enrolled (RCT)
Craig Hospital	Cynthia Harrison-Felix, PhD	A-16793.ai	15	A-16793.aii	31
Palo Alto Health Care System	Laura Howe, JD, PhD	A-16793.bi	7	A-16793.bii	30
Rehab Institute of Michigan	Scott Millis, PhD	A-16793.ci	7	A-16793.cii	14
Rehab Hospital of Indiana	Flora Hammond, MD	A-16793.di	7	A-16793.dii	28
University of Washington	Kathleen Bell, MD	A-16793.ei	8	A-16793.eii	32
Hunter Holmes McGuire VA	William Walker, MD	A-16793.fi	8	A-16793.fii	27

REPORTABLE OUTCOMES
No reportable outcomes as of yet.

CONCLUSIONS
No conclusions to report as of yet.

REFERENCES
None

APPENDICES
None